

IN THE CLAIMS

The claims pending in the application are reproduced below for the convenience of the Examiner.

1. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
a probe housing configured to be placed proximal to a tissue location which is being monitored;
light emission optics connected to ~~thesaid~~ housing and configured to direct radiation at ~~thesaid~~ tissue location;
light detection optics connected to ~~thesaid~~ housing and configured to receive radiation from ~~thesaid~~ tissue location; and
a processing device configured to process radiation from ~~thesaid~~ light emission optics and ~~thesaid~~ light detection optics and to compute ~~thesaid~~ metric wherein ~~thesaid~~ metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue, wherein the processing device receives and compares at least two sets of optical measurements from at least two different wavelengths, where absorption of light at the at least two different wavelengths is primarily due to water which is in the vascular blood and in the extravascular tissue, and where a ratio of the at least two measurements provides a measure proportional to the difference between the fractions of water in the blood and surrounding tissue location.
2. (Currently Amended) The device of claim 1 wherein ~~thesaid~~ body-tissue water content metric is computed as a fraction of bone-free-fat-free tissue content.

3. (Currently Amended) The device of claim 1 ~~further~~ comprising a display device connected to thesaid probe housing and configured to display thesaid water content.
4. (Currently Amended) The device of claim 1 wherein thesaid light emission optics and thesaid light detection optics are spaced between 1 and 5 mm from one another at thesaid tissue location.
5. (Currently Amended) The device of claim 1, wherein thesaid body-tissue metric is monitored intermittently.
6. (Currently Amended) The device of claim 1 wherein thesaid body-tissue metric is monitored continuously.
7. (Currently Amended) The probe housing of the device of claim 1 ~~further~~ comprising a spring-loaded probe configured to automatically activate a display device connected to thesaid probe housing when thesaid spring-loaded probe is pressed against and near a tissue location which is being monitored.
8. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
a probe housing configured to be placed proximal to a tissue location which is being monitored;
light emission optics connected to the housing and configured to direct radiation at the tissue location;
light detection optics connected to the housing and configured to receive radiation from the tissue location;

a processing device configured to process radiation from the light emission optics and the light detection optics and to compute the metric wherein the metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue; and

~~The probe housing of the device of claim 1 further comprising~~ a pressure transducer configured to measure the compressibility of tissue for deriving an index of a fraction of free water within thesaid tissue.

9. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
a probe housing configured to be placed proximal to a tissue location which is being monitored;

light emission optics connected to the housing and configured to direct radiation at the tissue location;

light detection optics connected to the housing and configured to receive radiation from the tissue location;

a processing device configured to process radiation from the light emission optics and the light detection optics and to compute the metric wherein the metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue; and

~~The probe housing of the device of claim 1 further comprising~~ a mechanism configured to ~~for mechanically induce~~inducing a pulse within thesaid tissue location to permit measurements related to the differences between an intravascular fluid volume and an extravascular fluid volume fractions under weak-pulse conditions.

10. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:

a probe housing configured to be placed proximal to a tissue location which is being monitored;

light emission optics connected to the housing and configured to direct radiation at the tissue location;

light detection optics connected to the housing and configured to receive radiation from the tissue location;

a processing device configured to process radiation from the light emission optics and the light detection optics and to compute the metric wherein the metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue; and

~~The probe housing of the device of claim 1 further comprising~~ a mechanism configured to for mechanically minimize~~minimizing~~ the pressure at ~~the said~~ tissue location to permit measurements related to the unperturbed fluid volume fraction in the tissue.

11. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:

a probe housing configured to be placed proximal to a tissue location which is being monitored;

light emission optics connected to the housing and configured to direct radiation at the tissue location;

light detection optics connected to the housing and configured to receive radiation from the tissue location;

a processing device configured to process radiation from the light emission optics and the light detection optics and to compute the metric wherein the metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue; and

~~The probe housing of the device of claim 1 further comprising~~ a mechanism configured to for mechanically induce~~inducing~~ pressure at ~~the said~~ tissue location to permit

measurement of the extravascular fluid fraction in the absence of the intravascular fluid fraction.

12. (Currently Amended). A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
a probe housing configured to be placed proximal to a tissue location which is being monitored;
light emission optics connected to the housing and configured to direct radiation at the tissue location;
light detection optics connected to the housing and configured to receive radiation from the tissue location;
a processing device configured to process radiation from the light emission optics and the light detection optics and to compute the metric wherein the metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue; and
~~The probe housing of the device of claim 1 further comprising~~ a mechanism configured to for mechanically varyvarying pressure at thesaid tissue location to permit measurement of both the intravascular and extravascular water fraction.

13. (Currently Amended) The device of claim 1, wherein thesaid light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen so that the biological compound of interest will absorb light at thesaid plurality of narrow spectral wavelengths and so that absorption by interfering species will be at a minimum, where a minimum absorption comprises[[is]] an absorption by an interfering species which is less than 10% of the absorption of the biological compound of interest.

14. (Currently Amended) The device of claim 1, wherein thesaid light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to be preferentially absorbed by tissue water, non-heme proteins and lipids, where preferentially absorbed

wavelengths comprise[[are]] wavelengths whose absorption is substantially independent of the individual concentrations of non-heme proteins and lipids, and is substantially dependent on the sum of the individual concentrations of non-heme proteins and water.

15. (Currently Amended) The device of claim 1, wherein thesaid light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to ensure that measured received radiation are substantially insensitive to scattering variations and such that the optical path lengths through the dermis at thesaid wavelengths are substantially equal.

16. (Currently Amended) The device of claim 1, wherein thesaid light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to ensure that measured received radiation from thesaid tissue location are insensitive to temperature variations, where thesaid wavelengths are temperature isosbestic in the water absorption spectrum or thesaid received radiation are combined in a way that substantially cancel temperature dependencies of thesaid individual received radiation when computing tissue water fractions.

17. (Currently Amended) The device of claim 1, wherein thesaid light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen from one of three primary bands comprising[[of]] wavelengths of approximately 950-1400 nm, approximately 1500-1800 nm and approximately 2000-2300 nm.

18. (Currently Amended) The device of claim 1, wherein thesaid light emission optics and thesaid light detection optics are mounted within thesaid probe housing and positioned with appropriate alignment to enable detection in a transmissive mode.

19. (Currently Amended) The device of claim 1, wherein thesaid light emission optics and thesaid light detection optics are mounted within thesaid probe housing and positioned with appropriate alignment to enable detection in a reflective mode.
20. (Currently Amended) The device of claim 1, wherein thesaid light emission optics and thesaid light detection optics are placed within a remote unit and are configured to~~which~~ deliver light to and receive light from thesaid probe housing via optical fibers.
21. (Currently Amended) The device of claim 1, wherein thesaid light emission optics comprise at least one of a (a) incandescent light source, (b) white light source, and (c) light emitting diode ("LED").
22. (Currently Amended) The device of claim 1, wherein thesaid processing device receives and compares at least two sets of optical measurements, where the at least first set of optical measurements corresponds to the detection of light whose absorption is primarily due to water and non-heme proteins, and where the at least second set of optical measurements corresponds to the detection of light whose absorption is primary due to water, and where a comparison of thesaid at least two optical measurements provides a measure of a fat-free or lean water fraction within thesaid tissue location.
23. (Currently Amended) The device of claim 1, wherein thesaid processing device receives and compares at least two sets of optical measurements, where thesaid at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of thesaid received radiation.
24. (Currently Amended) The device of claim 23, wherein thesaid processing device forms a weighted summation of thesaid combinations.

25. (Canceled).

26. (Currently Amended) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
a probe housing configured to be placed proximal to a tissue location which is being
monitored;
light emission optics connected to the housing and configured to direct radiation at the
tissue location;
light detection optics connected to the housing and configured to receive radiation from
the tissue location; and
a processing device configured to process radiation from the light emission optics and the
light detection optics and to compute the metric wherein the metric comprises a
ratio of the water content of a portion of patient's tissue in relation to the lean or
fat-free content of a portion of patient's tissue ~~The device of claim 1,~~ wherein
~~thesaid~~ water content metric, f_w^l is determined such

$$\text{that } f_w^l = \frac{\left[\sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[\sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[\sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[\sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}}, \text{ and where:}$$

p_n and q_m are calibration coefficients;

$R(\lambda)$ is a measure of a received radiation at a wavelength; and

$n=1-N$ and $m=1-M$ represent indices for a plurality of wavelengths which may comprise of the same or different combinations of wavelengths.

27. (Currently Amended) The tissue water fraction as determined in claim 26, wherein M and N are both equal to 3, the wavelengths indexed by m and n comprise of the same combination of

wavelengths, and ~~thesaid~~ first, second, third and fourth wavelengths are approximately 1180, 1245, 1275 and 1330 nm respectively.

28. (Currently Amended) A device for measuring a body-tissue metric using optical spectrophotometry, comprising:

a probe housing configured to be placed proximal to a tissue location which is being monitored;

light emission optics connected to ~~thesaid~~ housing and configured to direct radiation at ~~thesaid~~ tissue location;

light detection optics connected to ~~thesaid~~ housing and configured to receive radiation from ~~thesaid~~ tissue location; and

a processing device configured to process radiation from ~~thesaid~~ light emission optics and ~~thesaid~~ light detection optics to compute ~~thesaid~~ metric wherein ~~thesaid~~ body tissue metric comprises a quantified measure of a ratio of a difference between the water fraction in the blood and the water fraction in the extravascular tissue over the fractional volume concentration of hemoglobin in the blood.

29. (Currently Amended) The device of claim 28 wherein ~~thesaid~~ metric is a water balance index Q, such that:

$$Q = \frac{f_w^{IV} - f_w^{EV}}{f_h^{IV}} = a_1 \frac{(\Delta R / R)_{\lambda_1}}{(\Delta R / R)_{\lambda_2}} + a_0$$

where f_w^{IV} and f_w^{EV} are the fractional volume concentrations of water in blood and tissue, respectively, f_h^{IV} is the fractional volume concentration of hemoglobin in the blood, $([\square] \Delta R / R)_{\lambda}$ is the fractional change in reflectance at wavelength $[\square]_{\lambda}$, due to a blood volume change in the tissue, and a_0 and a_1 are calibration coefficients.

30. (Currently Amended) The device of claim 29 ~~further~~ comprising an input device configured to enable a user to input a fractional hemoglobin concentration in blood for use by ~~thesaid~~ processing device.

31. (Currently Amended) The device of claim 30 wherein ~~thesaid~~ processing device is ~~further~~ configured to compute a measure of the change in water content between the intravascular fluid volume ("IFV") and extravascular fluid volume ("EFV") using ~~thesaid~~ water index.

32. (Currently Amended) The device of claim 29 wherein ~~thesaid~~ first and second wavelengths are approximately 1320 nm and approximately 1160 nm respectively.

33. (Currently Amended) The device of claim 28 wherein ~~thesaid~~ light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen from one of three primary bands of wavelengths of approximately 950-1400 nm, approximately 1500-1800 nm and approximately 2000-2300 nm.

34. (Currently Amended) The device of claim 28 wherein ~~thesaid~~ body-tissue metric ~~further~~ comprises an integral of ~~thesaid~~ difference to provide a measure of the water that shifts into and out of the capillaries.

35. (Currently Amended) A method for measuring a body-tissue water content metric in a human tissue location as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:

~~placing a probe housing proximal to said tissue location;~~

emitting radiation at ~~thesaid~~ tissue location using light emission optics configured to

direct radiation at ~~thesaid~~ tissue location;

detecting radiation using light detection optics configured to receive radiation from
thesaid tissue location;
processing thesaid radiation from thesaid light emission optics and thesaid light detection
optics;
computing thesaid water content metric, wherein thesaid water content metric, f_w^I is

determined such that
$$f_w^I = \frac{\left[\sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[\sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[\sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[\sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}},$$
 and where:

p_n and q_m are calibration coefficients;

$R(\lambda)$ is a measure of a received radiation at a wavelength;
 $n=1-N$ and $m=1-M$ represent indexes for a plurality of wavelengths which may comprise
of the same or different combinations of wavelengths; and
displaying thesaid water content metric on a display device connected to thesaid probe
housing.

36. (Currently Amended) A method for measuring a body-tissue metric in a human tissue
location using optical spectrophotometry, comprising:

~~placing a probe housing proximal to said tissue location;~~
emitting radiation using light emission optics configured to direct radiation at thesaid
tissue location;
detecting radiation using light detection optics configured to receive radiation from
thesaid tissue location;
processing thesaid radiation from thesaid light emission optics and thesaid light detection
optics to compute thesaid metric wherein thesaid body fluid-related metric comprises
a quantified measure of a ratio of a difference between the water fraction in the blood
and the water fraction in the extravascular tissue over the fractional volume
concentration of hemoglobin in the blood; and
displaying thesaid metric or a quantity derived from thesaid metric on a display device.

37. (Currently Amended) The method of claim 36 wherein thesaid metric is a water balance index Q , such that:

$$Q = \frac{f_w^{IV} - f_w^{EV}}{f_h^{IV}} = a_1 \frac{(\Delta R / R)_{\lambda_1}}{(\Delta R / R)_{\lambda_2}} + a_0$$

where f_w^{IV} and f_w^{EV} are the fractional volume concentrations of water in blood and tissue, respectively, f_h^{IV} is the fractional volume concentration of hemoglobin in the blood, $(\Delta R / R)_{\lambda_1}$ is the fractional change in reflectance at wavelength λ_1 , due to a blood volume change in the tissue, and a_0 and a_1 are calibration coefficients.

38. (Currently Amended) A method of measuring a physiological parameter in a human tissue location, comprising:

emitting radiation at thesaid tissue location using light emission optics configured to direct radiation at thesaid tissue location;

detecting radiation using light detection optics configured to receive radiation from thesaid tissue location;

processing thesaid radiation from thesaid light emission optics and thesaid light detection optics; and

computing thesaid physiological parameter, wherein thesaid parameter is determined such

that it is equal to
$$\frac{\left[\sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[\sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[\sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[\sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}}, \text{ and where:}$$

p_n and q_m are calibration coefficients;

$R(\lambda)$ is a measure of a received radiation at a wavelength;

$n=1-N$ and $m=1-M$ represent indexes for a plurality of wavelengths which may comprise of the same or different combinations of wavelengths.

39. (Currently Amended) The method of claim 38, wherein thesaid physiological parameter comprises[[is]] the tissue water fraction in thesaid tissue location.

40. (Currently Amended) The method of claim 38, wherein thesaid physiological parameter comprises[[is]] an oxygen saturation value in thesaid tissue location.

41. (Currently Amended) The method of claim 38, wherein thesaid physiological parameter comprises[[is]] a fractional hemoglobin concentration in[[is]] thesaid tissue location.

42. (Currently Amended) The method of claim 38, wherein thesaid physiological parameter comprises[[is]] the fractional concentration of hemoglobin in a first set comprised of one or more species of hemoglobin with respect to the concentration of hemoglobin in a second set comprised of one or more hemoglobin species in tissue.

43. (Currently Amended) The method of claim 42 wherein the coefficients, p_n , ~~are chosen to~~ cancel the absorbance contributions from all tissue constituents except the hemoglobin species included in set 1 and the coefficients, q_m , are chosen to cancel the absorbance contributions from all tissue constituents except the hemoglobin species included in set 2.

44–47. (Canceled)

48. (New) The device of claim 8, wherein the processing device receives and compares at least two sets of optical measurements, wherein the at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of the received radiation.

49. (New) The device of claim 9, wherein the processing device receives and compares at least two sets of optical measurements, wherein the at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of the received radiation.

50. (New) The device of claim 10, wherein the processing device receives and compares at least two sets of optical measurements, wherein the at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of the received radiation.

51. (New) The device of claim 11, wherein the processing device receives and compares at least two sets of optical measurements, wherein the at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of the received radiation.

52. (New) The device of claim 12, wherein the processing device receives and compares at least two sets of optical measurements, wherein the at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of the received radiation.